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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,775	02/05/2004	Shuqi Chen	IQA-009.01	7895

25181 7590 06/06/2007

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EXAMINER	
YANG, NELSON C	

ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
06/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/773,775	CHEN ET AL.	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-84* is/are pending in the application.

4a) Of the above claim(s) *11-13,19-21,33-35,40-43,46,48-75 and 82-84* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,14-18,22-32,36-39,44,45,47 and 76-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/10/04, 11/13/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of claims 1-10, 14-18, 22-32, 36-39, 44-45, 47, 76-81 in the replies filed on February 26, 2007 and on November 13, 2006 is acknowledged.

2. Claims 11-13, 19-21, 33-35, 40-43, 46, 48-75, 82-84 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 26, 2007 and on November 13, 2006.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 18, 77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. With respect to claim 18, it is unclear how a substance such as silica would be capable of binding to a preselected component of a sample, reandering the claim ambiguous.

6. With respect to claim 77, it is unclear how the breakable seal is formed such that bursting of the breakable seal leaves the inner tubule surface substantially free of obstructions to fluid flow. Since applicant has not recited any structural features, and since the specification does not appear to disclose how the breakable seal is formed such that bursting of the breakable seal leaves the inner tubule surface substantially free of obstructions to fluid flow, it is assumed that any breakable seal would be capable of doing so.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 2, 5-10, 14-16, 22, 23, 29, 32, 36-37, 39, 47, 76, 77, 81 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al. [US 5,422,271].

With respect to claim 1, Chen et al. teach a device for amplifying and detecting nucleic acid material comprising a reaction compartment for amplifying a sample of nucleic acid material, a detection site for detecting amplified nucleic acid material (column 2, lines 34-52). Chen et al. further teach compartments with passageways that remain sealed, comprising three reagent compartments (column 3, lines 55-65).

9. With respect to claim 2, Chen et al. teach a detection compartment for optical detection, which would require transparent portion (column 4, lines 31-45).

10. With respect to claims 5-10, Chen et al. teach nucleic acids hybridized to a detection site comprising an immobilized probe (column 2, lines 20-25), which may be nucleic acids (column 6, lines 1-25).

11. With respect to claims 14-16, Chen et al. teach probes immobilized to a detection site (column 2, lines 20-25), wherein the detection site may comprise beads anchored in place (column 3, lines 55-60), which would essentially form a coating.

12. With respect to claim 22, Chen et al. teach an open end for introducing a sample (22, fig. 1).

13. With respect to claim 23, Chen et al. teach a closure cap (column 4, lines 48-50).

14. With respect to claim 29, Chen et al. teach a frame comprising rollers (column 4, lines 50-60).

15. With respect to claim 32, Chen et al. teach storage compartments comprising amplification material (column 2, lines 35-41).

16. With respect to claims 36-37, the seals taught by Chen et al. (column 9, liens 17-25) are peelable, as they are formed by different layers pressed together.

17. With respect to claim 39, Chen et al. teach compartments comprising wash solution (column 4, lines 29, 30), reagents need for PCR amplification (column 4, lines 2-5), compartments comprising members of a binding pair (column 4, lines 8-11), second wash solutions (elution buffer) (column 9, lines 65-67), dilution buffers (column 9, lines 50-52).

18. With respect to claim 45, the segments form a substantially contiguous array (fig. 1).

19. With respect to claim 47, Chen et al. teach a device for amplifying and detecting nucleic acid material comprising a reaction compartment for amplifying a sample of nucleic acid material, a detection site for detecting amplified nucleic acid material (column 2, lines 34-52). Chen et al. further teach compartments with passageways that remain sealed, comprising three reagent compartments (column 3, lines 55-65). Chen et al. teach compartments comprising wash solution (column 4, lines 29, 30), reagents need for PCR amplification (column 4, lines 2-5), compartments comprising members of a binding pair (column 4, lines 8-11), second wash solutions (elution buffer) (column 9, lines 65-67), dilution buffers (column 9, lines 50-52).

20. With respect to claim 76, the reagents may be in dry format, such as with the probe spots (column 9, lines 40-42).

21. With respect to claim 77, the seals taught by Chen et al. (column 9, liens 17-25) are formed by different layers pressed together and would therefore leave no obstructions behind.

22. 9With respect to claim 81, Chen et al. teach compartments comprising wash solution (column 4, lines 29, 30), reagents need for PCR amplification (column 4, lines 2-5), compartments comprising members of a binding pair (column 4, lines 8-11), second wash solutions (elution buffer) (column 9, lines 65-67), dilution buffers (column 9, lines 50-52).

23. Claims 1-3, 22-31, 38 44, 45, 77-80 are rejected under 35 U.S.C. 102(b) as being anticipated by Cusack et al. [US 5,380,665].

With respect to claim 1, Cusack et al. teach a first, second and third input ports with flexible tubing means coupled to the ports (first, second, and third segments) and to each other (abstract, column 2, lines 51-65). Since the tubes are flexible, they would be capable of expanding and compressing. Cussack further teach valving means between the tubings (column 3, lines 1-10), which may comprise check valves made from silicon rubber and which have a built in compression seal (column 10, lines 45-55). It is noted that since any seal is capable of being broken, the limitation of a "breakable seal" would read upon any seal.

24. With respect to claim 2, although Cusack et al. do not explicitly teach that a portion of the tubule is transparent, this would appear to be inherent in the tubing of Cusack et al., as bubble detectors are used, in which light is transmitted through the module to determine the presence of air in the fluid (column 12, lines 9-21), which would require the tubing to be transparent.

25. With respect to claim 3, Cusack et al. teach pneumatic air pump connected to the tubes (column 12, lines 39-50), which would act as pressure gates.

26. With respect to claims 22, 23, Cusack et al. teach inlet ports with diaphragm pumps (column 11, lines 30-55), which would act as caps, as the diaphragm pumps would block fluid from entering.

27. With respect to claim 24, Cusack et al. teach sample transfer tubes (column 6, lines 60-65).

28. With respect to claims 25-28, Cusack et al. teach inlet ports with diaphragm pumps (column 11, lines 30-55), which would act as caps, as the diaphragm pumps would block fluid from entering and would have a cavity and expandable chamber and would also be capable of acting as vents.

29. With respect to claims 29, 30, Cusack et al. teach a frame to which the tubule is mounted (47, fig. 6), which further contains an interface for receiving an open end of a tube (7, fig. 6).

30. With respect to claim 31, Cusack et al. teach inlet ports with diaphragm pumps (column 11, lines 30-55), which would act as caps, as the diaphragm pumps would block fluid from entering.

31. With respect to claim 38, the tubule comprises a proximal end and a distal end, wherein the second segment is distal to a first segment and the third segment is distal to the second segment (fig. 6, 1-6).

32. With respect to claims 44, 45, 80, the tubes form a substantially linear and contiguous array (fig. 6).

33. With respect to claim 77, Cussack further teach valving means between the tubings (column 3, lines 1-10), which may comprise check valves made from silicon rubber and which

have a built in compression seal (column 10, lines 45-55). It is noted that since any seal is capable of being broken, the limitation of a "breakable seal" would read upon any seal.

34. With respect to claims 78, 79, the tubes form a substantially linear and contiguous array (fig. 6).

Claim Rejections - 35 USC § 103

35. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

36. Claims 4, 17, 18, are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al. [US 5,422,271] in view of Presnell et al. [US 2003/0134390].

With respect to claims 4, 17, 18, Chen et al. teach the use of beads, but fail to teach the use of filters or silica beads.

Presnell et al., however, teach the use of silica beads, and further teach that these commercially available, and are methods for binding receptors to the beads are well known in the art (para. 0086). Presnell et al. further teach that the beads can be used for purifying samples, thus acting as a filter (para. 0142).

Therefore, one of ordinary skill in the art at the time of the invention would have been motivated to use silica beads in the device of Chen et al., and further to use them as filters, as suggested by Presnell et al., in order to more easily produce the device of Chen et al. by using resources commonly available at the time, and also to obtain better data by purifying the sample.

Conclusion

37. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NY

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